

# WORLD TRADE ORGANIZATION

RESTRICTED

**IP/C/W/268/Add.2**

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**Council for Trade-Related Aspects  
of Intellectual Property Rights**

Original: English

## **REVIEW OF LEGISLATION**

Follow-up questions posed by the United States

### Addendum

By means of a communication from the Permanent Mission of the United States, dated 20 June 2001, the Secretariat has received copies of the following follow-up questions that the United States has communicated to Argentina, Botswana, the Dominican Republic, Egypt, Kenya and the United Arab Emirates, respectively.

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### ARGENTINA

#### A. ENFORCEMENT

1. Please explain whether an interested party may file a sworn declaration with the customs authorities of Argentina to prevent the entry into commerce of infringing materials or to enable the seizure of infringing materials from abroad.
2. Please explain whether there are any laws or regulations in Argentina to ensure that government agencies do not infringe intellectual property rights in works such as computer software that is used in government agencies. Please describe any procedures that are in place to ensure that there is no unauthorized use of intellectual property rights by the government of Argentina.

### BOTSWANA

#### A. GEOGRAPHICAL INDICATIONS

1. Please explain whether the trademark registration authority of Botswana will refuse a trademark application if it contains a geographic indication that is not misleading with regard to the origin of the goods, their nature or other characteristics.

#### B. PATENTS

2. Please explain whether a patent owner has the right to prevent another from using a patented product under the laws of Botswana, as required under Article 28.1(a) of the TRIPS Agreement.

C. PROTECTION OF UNDISCLOSED INFORMATION

3. Please explain how the Intellectual Property Act of 1996 will be amended to include the protections that are required under Articles 39.2 and 39.3 of the TRIPS Agreement. Please address how the amended law will ensure that a second comer will not be allowed to rely on the data that is submitted to the regulatory authorities in support of a pioneer drug application, as required by the unfair commercial use provisions of Article 39.3 of the TRIPS Agreement.

DOMINICAN REPUBLIC

A. PATENTS

1. Please clarify whether purifications or isolations of materials found in nature are considered patentable subject-matter. If not, please explain which provisions of the TRIPS Agreement authorize their exclusion from patentable subject-matter. Also, if purifications or isolations are not considered inventions, please explain why they cannot be solutions to technical problems.

2. Please explain how the Dominican Republic has implemented the requirement in paragraph 7 of Article 70 of the TRIPS Agreement to permit applicants to add claims drawn to pharmaceutical products in applications that were pending on the effective date of the Industrial Property Law and that disclosed the products as well as the process of making them.

B. PROTECTION OF UNDISCLOSED INFORMATION

3. Please explain what measures are being taken to protect certain test and other data mentioned in Article 181 of the Industrial Property Law against unfair commercial use. Please clarify the duration of protection against unfair commercial use.

C. TRADEMARKS

4. Please explain any procedures for renewing a trademark registration that may be available under the laws of the Dominican Republic.

EGYPT

A. PATENTS

1. Please explain whether a known enzyme that was isolated from an animal and used as a contact lens cleaner would be patentable under the Egyptian draft law if this method of use is new, has an inventive step and industrial application.

2. Article 19(1) of the draft law appears to mandate that all applications directed to inventions in the pharmaceutical field not be granted until approval has been provided by the Egyptian Ministry of Health. How would the criteria that are to be used in evaluating such applications by this Ministry be established.

3. Draft Article 11 appears to provide that patent rights are "exhausted" if the patent owner has marketed the invention anywhere in the world. Please explain whether this authority is limited to products voluntarily placed on the market by the patent owner without restriction.

4. Draft Article 11 appears to exempt any "scientific activities" from the possibility of being patent infringement. Please explain in detail the "scientific activities" that are envisioned.

5. Draft Article 14 appears to require that applications related to biological matter include proof that the materials in the application were obtained legally in the country of origin. Please explain in detail the nature of the proof envisioned.

#### B. TRADEMARKS

6. Draft Article 96 would preclude trademark owners from refusing to terminate or renew a licensing agreement with good cause. Please explain in detail how a trademark owner would be able to ensure that a licensee maintained appropriate quality standards and fulfilled obligations of the licensing agreement.

#### C. PROTECTION OF UNDISCLOSED INFORMATION

7. No provision appears to give to a party that provides confidential test data to an Egyptian regulatory authority protection from unfair commercial use. Moreover, the last sentence of the English-language version of draft Article 57 appears to permit authorities to rely on test data submitted by another to prove that a similar product was safe and effective without any delay after the first party obtained marketing approval. Please explain how Egypt will provide protection from unfair commercial use of test data as required by Article 39.3 of the TRIPS Agreement.

### KENYA

#### A. GEOGRAPHICAL INDICATIONS

1. Please explain how Kenya ensures that interested parties can prevent the use of a geographical indication for wines and spirits that do not come from the place indicated in the geographical indication even when accompanied by expressions such as "kind", "type", "style", "imitation" or the like.

2. Please explain how Kenya ensures that interested parties can prevent the use of a geographical indication for wines or spirits that do not come from the place indicated in the geographical indication, even when the origin of the goods is indicated.

#### B. COPYRIGHT AND RELATED RIGHTS

3. Please explain how the requirement that copyright owners must apply for authentication under Article 36 of the proposed Copyright Act of 2000 ("proposed Act") is consistent with Article 5(2) of the Berne Convention, which states that the enjoyment and exercise of copyright should not be subject to any formality.

## UNITED ARAB EMIRATES

### A. PROTECTION OF UNDISCLOSED INFORMATION

1. Please explain in detail how Article 39 of the 1992 Patent and Industrial Design Law No. 44 includes the protections that are required under Article 39.3 of the TRIPS Agreement. Specifically, please explain how the law ensures that a second comer will not be allowed to rely on data that is submitted to the regulatory authorities in support of a pioneer drug application, as required by the unfair commercial use provisions of Article 39.3 of the TRIPS Agreement.
  2. Please explain whether there are any provisions in the laws of the United Arab Emirates that require applicants who are seeking marketing approval for a product to disclose to the regulatory authority the existence of a pending patent application or a patent relating to the same product.
  3. Please indicate how many grants of marketing approval for unauthorized copies of patented pharmaceutical products have been reversed in the last five years. Please address any ongoing efforts to reverse marketing approvals for unauthorized copies of patented pharmaceutical products and to prevent any further registrations of such products.
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